



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Robert James TRIBE

Serial No. 09/920,728

Art Unit: 3763

Filed: August 3, 2001

Examiner: DeSanto, Matthew F

For: SYRINGE PUMPS

Atty Docket: 0100/0131

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**DECLARATION OF PRIOR INVENTION IN THE UNITED STATES
OR IN A NAFTA OR WTO MEMBER COUNTRY
TO OVERCOME CITED PATENT OR PUBLICATION (37 C.F.R. § 1.131)**

PURPOSE OF DECLARATION

1. This declaration is to establish completion of the invention of this application in
the United States

the NAFTA country (name of country)

the WIPO country (Great Britain)

at a date prior to June 29, 2000 that is the effective date of the prior art

publication

patent Ford (US 6,551,277), and

patent publication

other

that were cited by the

examiner.

applicant.

2. The person making this declaration is (are):

the inventor(s).

only some of the joint inventor(s) (and a suitable excuse is attached for failure of the omitted joint inventor(s) to sign)

the party in interest (and a suitable explanation as why it is not possible to produce the declaration of the inventor(s) is attached)

FACTS AND DOCUMENTARY EVIDENCE

3. To establish the date of completion of the invention of this application, the following attached documents and/or models are submitted as evidence:

(check all applicable items below)

sketches

blueprints

photographs

reproduction(s) of notebook entries

model

supporting statement(s) by witness(es) (where verbal disclosures are the evidence relied upon)

Interference testimony

disclosure documents (Internal company design specification)

4. From these documents and/or models, it can be seen that the invention in this application was made

on

at least by the date of June 28, 2000 which is a date earlier than the effective date of the reference.

DILIGENCE

5. Below is a statement establishing the diligence of the applicants, from the time of their conception, to a time just prior to the date of the reference, up to the:

- actual reduction to practice; and/or
- filing of UK 0020060.0 from which Application No. 09/920,728 claims priority.

The invention disclosed in the specification of U.S. Application 09/920,728 was conceived at a date at least prior to June 29, 2000, as evidenced by the hereto attached Internal Company Design Specification (ICDS) relating to the software for the syringe pump disclosed in the '728 specification. From the date at least of the ICDS to the actual reduction to practice of the claimed invention and/or the filing date August 16, 2000 of the application (UK 0020060.0) from which the '728 application claims priority, the inventors were actively and diligently working to put into practice the claimed invention.

TIME OF PRESENTATION OF THE DECLARATION

This declaration is submitted prior to final rejection.

- This declaration is submitted with the first response after final rejection, and is for the purpose of overcoming a new ground of rejection or requirement made in the final rejection.

This declaration is submitted after final rejection. A showing under 37 C.F.R. § 1.116(b) is submitted herewith.

DECLARATION

6. As a person signing below:

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

Inventor(s)

Full name of sole or first inventor Robert James Tribe

Inventor's signature _____

Date _____ Country of Citizenship UK

Residence Loughton, Essex IG 10 2QN, England

Post Office Address 38 Goldings Road, Loughton, Essex IG10 2QN, England

Full name of second joint inventor Christopher Thomas Pickles

Inventor's signature Christopher

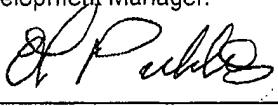
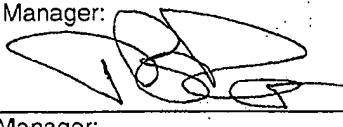
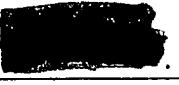
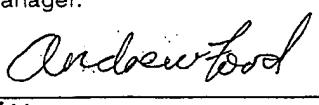
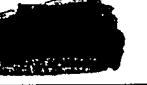
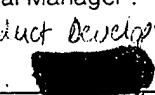
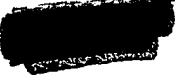
Date 15th June 2009 Country of Citizenship UK

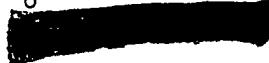
Residence Axminster, Devon, England

Post Office Address 19 Fosseway Close, Axminster, Devon EX13 5LW, England

SIMS GRASEBY

SOFTWARE SPECIFICATION FOR THE 4000 SERIES OF SYRINGE PUMPS

Software Development Manager: 	Date: 
Product Manager: 	Date: 
Project Manager: 	Date: 
Technical Manager: New Product Development 	Date: 

Document No: TS/151-002
Filename: TS 151-002 Issue 6.doc
Issue: 6
Date: 

Issue	Date	Author	Reason for Issue
Draft		Fiona Roden	For review
A		Fiona Roden	For quotation purposes
B		Fiona Roden	For review
C		Fiona Roden	Following review
1		Chris Pickles, Fiona Roden	Following issue of other specifications and comments from VEGA. Safety requirements added, system alarms expanded.
1A		Chris Pickles	Requirement numbers (as hidden text) added to document in the version that was uploaded into the RTD (by VEGA).
1B		VEGA	Document updated to incorporate all RCFs, Addendums and Resolved Issue texts.
1C		VEGA/Graseby	Document reviewed and updated.
2		VEGA/Graseby	Released following re-baselining activity at VEGA. Note document not formerly released.
2A		VEGA/Graseby	Released following informal review changes
3		VEGA/Graseby	Released following review for inclusion in contract. CD/ECR ref.: ECR 0403
4		VEGA/Graseby	Section 4 updated following review. CD/ECR ref.: ECR 0410
5		VEGA	Issue incorporates RCFs 351.01, 357.01, 359.01, 360.01, 360.02, 361.01, 366.01, 601, 602, 603, 604, 605, 606, 607, 608, 609, 610, 611, 612, 613, 614, 615, 620, 621, 622, 623, 624, 626, 627, 628, 629, 630, 631, 632, 633, 634, 635, 636, 638, 639, 640, 641, 642, 643, 644 & 645. CD/ECR ref.: ECR 0441
6		VEGA	Issue incorporates RCFs 367.01, 369.01, 371.01, 373.01, 375.01, 377.01, 379.01, 380.01, 382.01, 384.01, 385.01, 386.01, 378.02,

			374.01, 374.02, 374.03, 383.01, 389.01, 391.01, 392.01, 393.01, 396.01, 399.01, 403.01 & 406.01, 407.01. CD/ECR ref.: ECR 0451
--	--	--	--

Contents

1. GLOSSARY.....	8
2. INTRODUCTION.....	9
2.1 INTERPRETATION OF CRS.....	9
2.2 USER INTERFACE.....	10
2.2.1 Display.....	10
2.2.2 Rotary knob.....	10
2.2.3 Keypad.....	10
2.2.4 Sounder.....	10
2.2.5 LEDs.....	11
2.2.6 Lockable cover.....	11
3. DISPLAY DESCRIPTION	12
3.1 ICONS	12
3.1.1 Pump status icon.....	12
3.1.2 Help icon	12
3.1.3 Battery status icon.....	12
3.1.4 Near Empty icon.....	13
3.1.5 INFO icon	13
3.2 SCROLL BAR.....	13
3.3 ON-SCREEN OCCLUSION INFORMATION	14
3.3.1 Dry-Side occlusion information	14
3.3.2 In-line occlusion information.....	15
3.4 MESSAGE LINE	15
4. SAFETY REQUIREMENTS	18
4.1 CRITICALITY LEVELS	18
4.2 FAULT TOLERANCE TIME	18
4.3 MITIGATION OF HAZARDS ARISING OUT THE RISK MANAGEMENT PROCESS	18
4.3.1 Uncontrolled branch to fast traverse [SSR001].....	18
4.3.2 Over-infusion or under-infusion due to incorrect rate value entry [SSR002]	19
4.3.3 Over-infusion or under-infusion due to derived motor step rate calculation error [SSR003]	19
4.3.4 Over-infusion or under-infusion due to motor speed error [SSR004].	20
4.3.5 AC power failure during infusion [SSR005].....	20
4.3.6 Battery discharged during infusion [SSR006]	20
4.3.7 Battery integrity monitoring [SSR007]	20
4.3.8 Under-infusion due to failure to detect syringe empty [SSR009].....	21
4.3.9 Under-infusion or Over-infusion due to volume infused measurement or calculation error [SSR010].....	21
4.3.10 Under-infusion or Over-infusion due to mass infused calculation error [SSR011].....	21
4.3.11 Under-infusion or Over-infusion due to syringe size measurement error [SSR012]	22
4.3.12 Inappropriate Pump State [SSR036].....	22
4.3.13 Under-Infusion Due To Unintentional Power Off [SSR037]	23
4.3.14 Over infusion due to Free-flow (SSR044)	23
4.4 MITIGATION OF EVENTS ARISING OUT THE RISK MANAGEMENT PROCESS	24
4.4.1 EOT sensor failure [SSR013].....	24
4.4.2 First touch sensor (FTS) failure [SSR014].....	24
4.4.3 Clamping fingers open sensor failure [SSR015].....	24
4.4.4 Dry-side pressure sensor failure [SSR016].....	24
4.4.5 In-line pressure sensor failure [SSR017]	25
4.4.6 External watchdog failure (primary processor) [SSR018].....	26
4.4.7 COP watchdog failure (secondary processor) [SSR019].....	26
4.4.8 Inter-processor communications failure [SSR020].....	26
4.4.9 PCA Handset fault (applies to PCA and PCS infusions only) [SSR021]	26
4.4.10 PCA switch fault (applies to PCA and PCS infusions only) [SSR022].....	27
4.4.11 Motor direction wrong [SSR023]	27
4.4.12 Motor turns when it should be stopped [SSR024].....	27
4.4.13 Syringe tampered with once syringe brand and size confirmed by user [SSR025].....	27

4.4.14	Syringe size changed at syringe change during an infusion [SSR026]	28
4.4.15	Data critical to an infusion corrupted [SSR027]	28
4.4.16	Program branches to random location [SSR028]	28
4.4.17	Stack overflow or underflow [SSR029]	29
4.4.18	RAM failure [SSR030]	29
4.4.19	ROM corruption (program memory) [SSR031]	29
4.4.20	NV memory corruption [SSR032]	29
4.4.21	Unused interrupt invoked [SSR033]	30
4.4.22	Display data corrupted [SSR034]	30
4.4.23	Sounder failure [SSR035]	30
4.4.24	Rotary Knob Control [SSR038]	30
4.4.25	Keypad Control [SSR039]	31
4.4.26	Pump Initialisation [SSR040]	31
4.4.27	Infusion Units [SSR042]	31
4.4.28	Alarms [SSR043]	31
5.	POWER UP SEQUENCE	32
5.1	POWER UP FOR NON-TCI INFUSION MODES	35
5.2	POWER UP FOR TARGET CONTROLLED INFUSION (TCI) MODE	37
5.3	POWER DOWN SEQUENCE	38
5.4	POWER FAIL	38
5.5	STANDBY	39
6.	PARAMETER ENTRY	40
6.1	ENTERING THE INFUSION RATE AND UNITS	41
6.1.1	Infusion rate calculations	43
6.2	ENTERING THE PATIENT WEIGHT	44
6.3	ENTERING THE DRUG CONCENTRATION	44
6.3.1	Entering a "user mixed" drug concentration:	45
6.3.2	Entering a "pre-mixed" drug concentration	47
6.4	DISPLAY DATA ENTRY RULES AND RANGES	48
6.5	FLOW RATE VALIDATION	52
6.6	REVIEW SCREEN	54
7.	THE PROGRAMMING STATE	57
7.1	GENERAL NOTES ON PROGRAMMING THE PUMP	60
7.2	SETTING UP A CONTINUOUS INFUSION	61
7.3	SETTING UP AN INTERMITTENT INFUSION	62
7.4	SETTING UP A PRESET VOLUME INFUSION	65
7.5	SETTING UP A PRESET TIME INFUSION:	66
7.6	SETTING UP A PCA INFUSION	67
7.7	SETTING UP A PCS INFUSION	70
7.8	SETTING UP A TCI INFUSION	73
7.8.1	Introduction	73
7.8.2	Selection of parameters	73
7.8.3	INFO sequence	76
7.8.4	TCI Menu parameters	83
7.9	SETTING UP A CIRCADIAN RHYTHM INFUSION	84
8.	THE RUNNING STATE	86
8.1	EXAMPLE RUNNING SCREENS	86
8.2	FUNCTIONS AVAILABLE IN THE RUNNING STATE	90
8.3	KEEP VEIN OPEN (KVO)	93
8.3.1	Definition of KVO	93
8.3.2	Entry into KVO	93
8.3.3	KVO rate	94
8.3.4	Operational modes in which KVO supported	94
9.	THE SUSPENDED STATE	96
10.	LOADING/UNLOADING A SYRINGE	100
10.1	PUSHER LOCATION	100
10.2	SYRINGE LOADING	100

10.2.1	Fault detection during syringe loading	102
10.3	MOVE TO HOME.....	103
10.3.1	Fault detection during move to home.....	103
10.4	UNLOADING A SYRINGE	103
10.5	SENSOR TESTS	104
10.6	ACHIEVING A KNOWN STATE FROM UNUSUAL STARTING CONDITIONS	104
10.7	DEFINITIONS	104
10.8	VALIDATION AND CONFIRMATION OF SYRINGE SIZE AND BRAND (NON-TCI)	105
10.9	VALIDATION OF SYRINGE SIZE AND DRUG (TCI)	106
11.	ADMINISTERING A BOLUS	107
11.1	HANDS ON BOLUS INFUSION	107
11.2	HANDS FREE (PRE-SET) BOLUS INFUSION	109
12.	PURGING THE LINE	112
13.	THE TOTALISER.....	113
13.1	EXAMPLE PCA TOTALISER SCREEN	115
13.2	EXAMPLE TCI TOTALISER SCREEN.....	116
13.3	EXAMPLE PCS TOTALISER SCREEN	116
14.	GRAPHICS	117
14.1	INFUSION PROFILES	120
14.1.1	Normal infusion profile	120
14.1.2	PCA, PCS.....	121
14.1.3	TCI.....	122
14.2	IN-LINE PRESSURE TREND GRAPH	123
15.	WARNINGS AND ALARMS.....	124
15.1	WARNINGS	125
15.1.1	One-off warnings.....	125
15.1.2	Repeated warnings	128
15.1.3	System warnings.....	131
15.2	ALARMS	133
15.2.1	Operating alarms.....	133
15.2.2	System alarms	137
16.	THE SET-UP STATE.....	143
16.1	SET-UP STATE : HELP	145
16.2	SET-UP STATE : HISTORY.....	147
16.3	SET-UP PARAMETER DEPENDENCY TABLE	148
17.	THE CONFIGURATION STATE.....	150
17.1	CONFIGURATION PARAMETERS	150
17.2	CONFIGURATION PARAMETER DEPENDENCY TABLE	155
18.	THE TECHNICIAN STATE.....	157
18.1	TECHNICIAN PARAMETER DEPENDENCY TABLE	159
19.	THE GRASEBY ONLY STATE	160
20.	HISTORY	162
21.	COMMUNICATIONS	168
21.1	EXTERNAL COMMUNICATIONS	168
21.1.1	Front panel, external controller interoperability.....	168
21.1.2	External Communications when in 'Fast Traverse'.....	170
22.	NEAR EMPTY DETECTION.....	171
23.	OCCLUSION DETECTION.....	173
23.1	IN-LINE PRESSURE SENSING	173
23.2	DRY SIDE OCCLUSION SENSING	173
24.	SYRINGE TAMPER DETECTION.....	176
25.	POWER MANAGEMENT	177

25.1	BATTERY MANAGEMENT.....	177
25.2	POWER MANAGEMENT SYSTEM.....	177
26.	MOTOR CONTROL.....	178
26.1	PUMPING (TIMED COMMUTATION) MODE DETAILS	178
26.2	MOTOR MONITORING	178
26.3	INFUSION MONITORING	180
27.	PUMP CONFIGURATION	183
27.1	LANGUAGE	183
27.2	PUMP PROGRAMMING	183
27.2.1	Introduction.....	183
27.2.2	Program Loader Communications	183
27.2.3	Reprogramming Sequence	184
27.2.4	Fault detection.....	184
27.2.5	Provision of programs to be loaded to the PC	184
28.	CROSS REFERENCE TO CUSTOMER REQUIREMENTS SPECIFICATION	185
29.	APPENDIX 1.....	189

23. OCCLUSION DETECTION

A block in the infusion line will cause a build up of pressure on the pusher side of the blockage. This can be detected through an increase in pressure detected on the dry-side sensor, or using the in-line sensor when fitted. A low pass filter (i.e. averaging), which smoothes the signal, will be used to ensure that one-off high occlusion readings do not cause an occlusion alarm. On detection of an occlusion, the pusher is 'backed off' to ensure that when the blockage is cleared, a large dose is not administered to the patient.

[2074 Occlusion detection shall be performed when Running.] [2073 If the optional in-line pressure sensor is fitted then the in-line pressure sensor shall be used to detect occlusions using the occlusion pressure limit as setup by the user in screen figure 3-2.] [1851 If the in-line pressure sensor is not fitted then the dry side pressure sensor shall be used to detect occlusions using the occlusion pressure limit as setup by the user in screen figure 3-1.]

This means that occlusion detection using the dry-side is suppressed when the in-line sensor is being used. However, the dry-side is used to back-up the operation of the in-line sensor in the following way: [1206 If the in-line measured pressure is beneath the occlusion threshold, but the dry-side pressure exceeds level 5, an occlusion alarm shall result.]

An occlusion may be detected by comparing the sensor reading with the set occlusion limit. [1115 On detection of occlusion, the pump must stop infusing and generate an occlusion alarm.]

23.1 In-line Pressure Sensing

[1207 When running, an in-line pressure sensor pressure reading should be obtained at least once every 5 seconds.]

[1116 On detection of an occlusion, the pusher should be 'backed off' until either the pressure reading (using 16x rolling average) has fallen to less than 10% of the occlusion pressure limit, or 200 motor steps have been taken.]

23.2 Dry Side Occlusion Sensing

[1194 When running, a reading should be obtained of the pusher force at least every 5 seconds.]

Note that the force required for each of the occlusion levels will be dependent on the diameter of the syringe loaded. [2075 The software shall identify the 'level' from the syringe nominal volume and sensor reading as defined in Table 23-1.]

	2ml top	2/3ml	5ml	10ml	20 / 25ml	30ml	50 ml	Display	Level
Less than	0.7	1.4	2.6	3.8	6.7	8.6	13.5	0 bar	0.0
Equal to or greater than	0.7	1.4	2.6	3.8	6.7	8.6	13.5	1 bar	0.1
Equal to or greater than	1.0	2.0	3.7	5.4	9.6	12.1	19.0	2 bar	0.2
Equal to or greater than	1.3	2.6	4.8	7.0	12.4	15.7	24.5	3 bar	1.0
Equal to or greater than	1.6	3.2	5.9	8.7	15.3	19.3	30.0	4 bar	1.1
Equal to or greater than	1.9	3.8	7.0	10.3	18.1	22.8	35.5	5 bar	1.2
Equal to or greater than	2.1	4.3	8.1	11.9	21.0	26.4	41.0	6 bar	2.0
Equal to or greater than	2.4	4.9	9.3	13.5	23.8	30.0	46.4	7 bar	2.1
Equal to or greater than	2.7	5.5	10.4	15.1	26.7	33.5	51.9	8 bar	2.2
Equal to or greater than	3.0	6.1	11.5	16.7	29.5	37.1	57.4	9 bar	3.0
Equal to or greater than	3.3	6.7	12.6	18.3	32.4	40.7	62.9	10 bar	3.1
Equal to or greater than	3.6	7.3	13.7	19.9	35.2	44.2	68.4	11 bar	3.2
Equal to or greater than	3.9	7.9	14.8	21.6	38.1	47.8	73.9	12 bar	4.0
Equal to or greater than	4.2	8.5	15.9	23.2	40.9	51.3	79.4	13 bar	4.1
Equal to or greater than	4.5	9.1	17.0	24.8	43.8	54.9	84.9	14 bar	4.2
Equal to or greater than	4.8	9.7	18.1	26.4	46.6	58.5	90.4	15 bar	5.0

Table 23-1

Notes to Table 23-1:

1. The body of the table shows the figure the force must be equal to or exceed to display a given number of bars
2. The TOP 2ml syringe is an exception in that it requires a separate column.
3. The level referred to in the right hand column of the table is that displayed as 'current pressure reading' on Figure 3-1 of the Software Specification (note the value shown on figure 3-1 is illustrative only).

4. The highest number of bars will always be displayed, e.g. a force of 7N with a 3ml syringe will display 10 bars.

[2076 On detection of an occlusion, the pusher should be 'backed off' until either the force reading (using 16x rolling average) has fallen to less than 10% of the occlusion force limit, or 200 motor steps have been taken.]